

**REMARKS**

Claims 22-48 are pending in the present application. Claims 22, 26-28, 30, 31, 33-36, 39 and 42-46 have been amended. Claims 47 and 48 have been presented herewith.

**Telephone Interview**

Applicants respectfully note the courtesy extended by Examiner Fritchman and Supervisor Warden during the telephone interview conducted on January 27, 2009. During the telephone interview, the Examiner acknowledged that the arguments presented by Applicants' representative regarding the Oberhardt reference (U.S. Patent No. 6,251,615) and the Stave et al. reference (U.S. Patent No. 6,663,833) appeared persuasive, and upon further consideration would likely be withdrawn. The Examiner however cautioned that further consideration would be necessary subsequent receipt of a corresponding response to the current Office Action dated August 19, 2008. The content of the discussion during the telephone interview will be reflected in the following remarks.

**Priority Under 35 U.S.C. 119**

Applicants note the Examiner's acknowledgment of the Claim for Priority under 35 U.S.C. 119, and receipt of the certified copy of the priority document.

**Information Disclosure Statement**

An Information Disclosure Statement has been filed on November 19, 2008.

**The Examiner is respectfully requested to acknowledge receipt of the Information Disclosure Statement, and to confirm that the documents listed therein have been considered and will be cited of record in the present application.**

**Drawings**

Enclosed is a drawing Annotated Sheet, wherein Fig. 9 has been corrected to include reference numerals which correspond to a sampling channel (111), a liquid blocking valve (116), a bore (122), a first orifice (113), a first electrode pair (117,120), a second orifice (109) and a second electrode pair (106,121), as described on pages 20 and 21 of the application. Also enclosed is one (1) drawing Replacement Sheet, incorporating the above noted corrections. **The Examiner is respectfully requested to acknowledge receipt and approval of the drawing Replacement Sheet.**

**Claim Rejections-35 U.S.C. 103**

Claims 22, 23, 35-37 and 40-46 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt reference (U.S. Patent No. 6,251,615) in view of the Stave et al. reference (U.S. Patent No. 6,663,833). This rejection is respectfully

traversed for the following reasons.

The cartridge for counting and discriminating a plurality of types of blood cells in a blood sample in one counting operation of claim 22 comprises a housing which includes in combination among other features a first liquid storage chamber "that holds a lysing reagent that lyses and dilutes erythrocytes while maintaining counting ability of other blood cell types"; a first mixing chamber and a first collection chamber; first cell characterization means "for characterizing and counting the plurality of types of blood cells passing through the first orifice"; a bore; and a first sampling member. Applicants respectfully submit that the cartridge of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner for at least the following reasons.

The Oberhardt reference as relied upon by the Examiner discloses cell analysis methods which involve the capture of or delay in transit time of cells with specific surface molecules by means of affinity interactions with test surfaces, as described beginning in column 2, line 24. As described beginning in column 3, line 25 of the Oberhardt reference, a disclosed method includes contacting the cells to a surface portion of a conduit (capture zone), and imaging the surface portion, whereby a response file is generated for each of the plurality of cells from digital information for each of at least two different types of emitted light. Figs. 6A – 6C of the Oberhardt reference show specific receptor molecules 30 strongly attached to surface 29 within the capture zone. The details of the cell capture cartridge is shown in Fig. 4 of the Oberhardt reference, wherein light waves from one or more light sources from a single

line source 34 strike capture zone 24. Also, Fig. 12 shows a high resolution digital camera such as a CCD detector array 73 and camera electronics 74.

Accordingly, the Oberhardt reference as relied upon performs cell analysis using capture zones and light imaging. The Oberhardt reference does not include first cell characterization means for characterizing and counting a plurality of types of blood cells passing through a first orifice between a first mixing chamber and a first collection chamber, as would be necessary to meet the features of claim 22.

As further described in column 3, lines 21-24 of the Oberhardt reference, the disclosed system is used to analyze blood cell types **without requiring lysis of red blood cells**. Since the system of the Oberhardt reference analyzes without lysis of red blood cells, the Oberhardt reference clearly does not include a first liquid storage chamber that holds a lysing reagent that lyses and dilutes erythrocytes while maintaining counting ability of other blood cell types, as would be necessary to meet the further features of claim 22.

The Examiner has asserted in the paragraph bridging pages 3-4 of the current Office Action dated August 19, 2008, that the Oberhardt reference teaches analyzing and counting subsets of blood cells in column 1, lines 27-32, and also teaches of a segmented stream of liquid being sent through an open bore in column 21, lines 35-36.

However, column 1, lines 27-32 of the Oberhardt reference is descriptive of hematology analyzers of background prior art, and is not descriptive of the cell analysis system of the preferred embodiments of the Oberhardt reference. Moreover, column

21, lines 29-38 of the Oberhardt reference describes another prior art system, not a cell analysis system of the preferred embodiments of the Oberhardt reference.

On the other hand, the Stave et al. reference as secondarily relied upon discloses an assay device for detection of analyte in a sample. As described beginning in column 4, line 5 of the Stave et al. reference, the detection membrane of the preferred device is a substrate upon which is immobilized means for detecting the labeled reagent that has reacted either directly or indirectly with analyte in the sample. Detection of the label can be visual or with the aid of a detector such as a spectrophotometer or a reflectometer. As further described beginning in column 12, line 39 of the Stave et al. reference, binding molecules may be labeled directly with a detectable label, whereby labels for use in immunoassays are generally known and include enzymes, radiol isotopes, and fluorescent, luminescent and chromogenic substances for instance.

As further described beginning in column 14, line 18 of the Stave et al. reference, the sample delivery means as shown in Figs. 2 and 3 contains a sample separating membrane between a sample well and a sample capillary tube for retaining cellular or particulate components of the sample, to thereby prevent delivery of these components into the liquid flow channel. This excludes passage of large sample components such as blood cells for example, but allows blood plasma containing smaller molecules such as viruses, bacteria or drugs to pass through into the sample capillary tube for analysis.

As further described in the abstract, the preferred detection membrane is an immunochromatographic test strip containing immobilized reagents.

Accordingly, the Stave et al. reference as secondarily relied upon also fails to disclose a first liquid storage chamber that holds a lysing reagent that lyses and dilutes erythrocytes while maintaining counting ability of other blood cell types, in combination with first cell characterization means for characterizing and counting a plurality of types of blood cells passing through a first orifice between a first mixing chamber and a first collection chamber. The Stave et al. reference does not overcome the above noted deficiencies of the primarily relied upon Oberhardt reference. Accordingly, Applicants respectfully submit that the cartridge of claim 22 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection, insofar as it may pertain to claims 22, 23, 35-37 and 40-46, is improper for at least these reasons.

With further regard to this rejection, the Examiner has alleged that the Stave et al. reference teaches a second mixing chamber and a second collection chamber separated by a second wall containing a second orifice, and second cell characterization means. However, as noted previously, the sample separating membrane as described with respect to Figs. 2 and 3 of the Stave et al. reference excludes passage of large sample components such as cells, thus preventing delivery of these components into the liquid flow channel. This allows smaller molecules to pass through into the sample capillary tube for analysis. The Stave et al. reference does not disclose or suggest the use of a second mixing chamber, a second collection chamber, and second cell characterization means for characterizing and counting a

plurality of types of blood cells that pass through a second orifice between the second mixing chamber and the second collection chamber, in combination with a first mixing chamber, a first collection chamber and first cell characterization means, as would be necessary to meet the features of respective claims 35 and 36. Applicants therefore respectfully submit that the claims 35 and 36 would not have been obvious in view of the prior art as relied upon by the Examiner taken singularly or together, and that this rejection of claims 35 and 36 is improper for at least these additional reasons.

Claims 24, 25, 33 and 34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt and Stave et al. references, in further view of the Ledis et al. reference (U.S. Patent No. 5,731,206). Claim 26 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt, Stave et al. and Ledis et al. references, in further view of the Sangha reference (U.S. Patent No. 5,334,502). Claims 27 and 28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt and Stave et al. references, in further view of the Sangha reference. Claims 29 and 31 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt and Stave et al. references, in further view of the Becker et al. reference (U.S. Patent No. 5,045,474). Claim 30 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt and Stave et al. references, in further view of the Li et al. reference (U.S. Patent No. 5,882,934). Claim 32 has been rejected under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt, Stave et al. and Becker et al. references, in view of the Li et al. reference. Claim 38 has been rejected

under 35 U.S.C. 103(a) as being unpatentable over the Oberhardt and Stave et al. references, in view of the Seymour reference (U.S. Patent No. 5,393,496).

Applicants respectfully submits that the above noted secondary references do not overcome the deficiencies of the primarily relied upon prior art, and that these respective rejections are improper for at least these reasons.

### **Conclusion**

The Examiner is respectfully requested to reconsider and withdraw the corresponding rejections, and to pass the claims of the present application to issue, for at least the above reasons.

In the event that there are any outstanding matters remaining in the present application, please contact Andrew J. Telesz, Jr. (Reg. No. 33,581) at (571) 283-0720 in the Washington, D.C. area, to discuss these matters.

Pursuant to the provisions of 37 C.F.R. 1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to February 19, 2009, for the period in which to file a response to the outstanding Office Action. The required fee of \$1110.00 should be charged to Deposit Account No. 50-0238.



If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment for any additional fees that may be required, or credit any overpayment, to Deposit Account No. 50-0238.

Respectfully submitted,

VOLENTINE & WHITT, P.L.L.C.



Andrew J. Telesz, Jr.  
Registration No. 33,581

11951 Freedom Drive, Suite 1260  
Reston, Virginia 20190  
Telephone No.: (571) 283-0720  
Facsimile No.: (571) 283-0740

Enclosures: One (1) drawing Annotated Sheet  
One (1) drawing Replacement Sheet

# ANNOTATED SHEET

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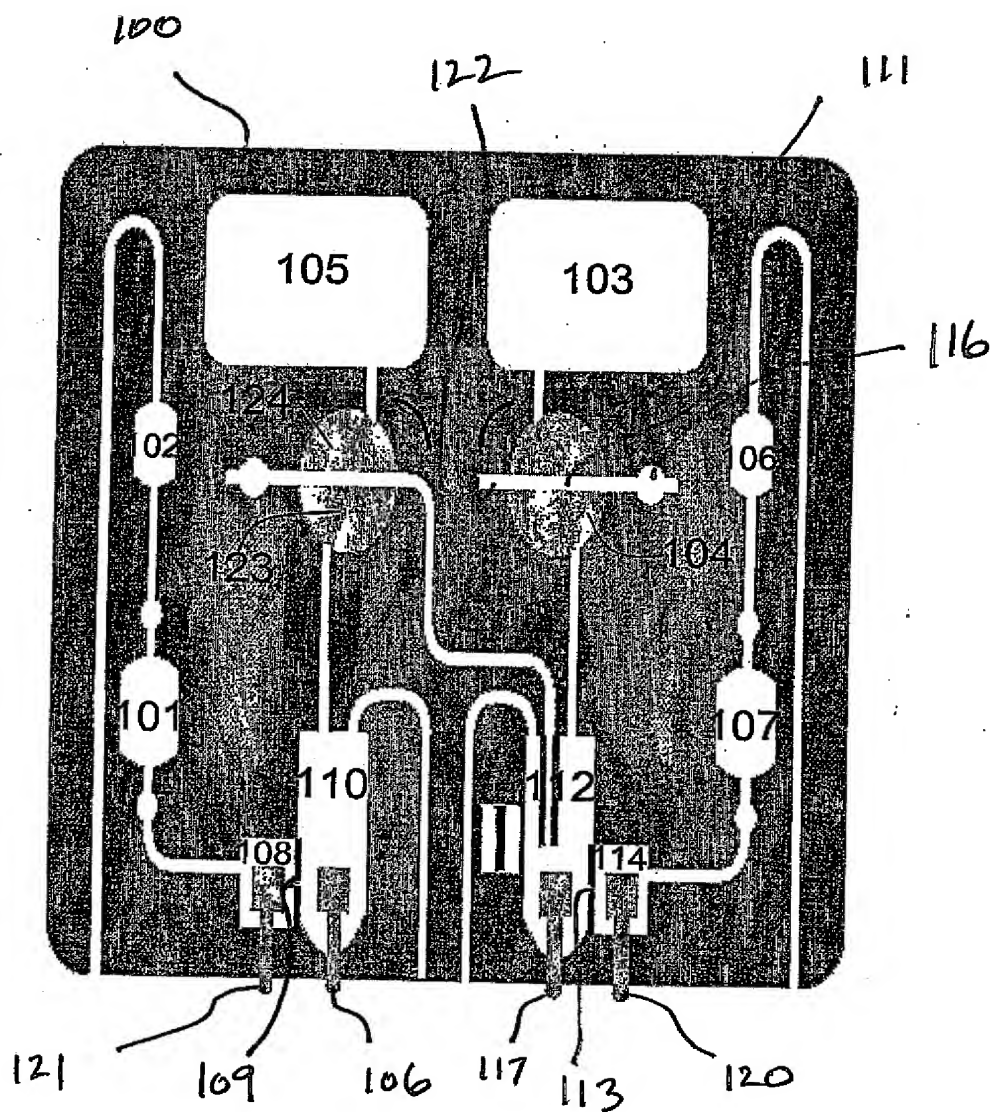


Fig. 9